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June 2, 2021

VIA ECF

The Honorable Thomas I. Vanaskie (Ret.)
Special Master for Discovery
Stevens & Lee
1818 Market Street, 29th Floor
Philadelphia, PA 19103

Re: In re: Valsartan, Losartan, and Irbesartan Products Liability Litigation
USDC District of New Jersey, Camden Division, No. 1:19-md-2875-RBK-JS

Dear Judge Vanaskie:

The Aurobindo entities (hereinafter "Aurobindo") respectfully submit this letter in response to Plaintiffs' letter filed on May 26, 2021 (the "May 26 Letter"), which rehashes arguments that this Court has already found unavailing. Plaintiffs' May 26 Letter provides no evidence of bad faith on the part of Aurobindo or of prejudice to Plaintiffs. Plaintiffs' renewed request for extraordinary sanctions should be denied.

I. Plaintiffs Failed To Meet and Confer With Aurobindo Before Filing The May 26 Letter



As a threshold matter, Plaintiffs failed to meet and confer with counsel for Aurobindo before filing their letter as required by Federal Rule of Civil Procedure 37 and Local Rule 37.1. Plaintiffs first emailed Aurobindo's counsel concerning these latest issues on May 26 at 11:15 am -- a mere four hours before submitting their May 26 letter to Your Honor. Plaintiffs made no meaningful effort to work through these issues with Aurobindo and to attempt to resolve them before burdening this Court. Aurobindo offered to discuss the forthcoming productions further with Plaintiffs to avoid any prejudice. Plaintiffs should not be rewarded for their failure to comply with the meet and confer requirement. In fact, if Plaintiffs had met and conferred as required, Aurobindo would have had the opportunity to explain to them how the assertions and assumptions underlying their latest submission are incorrect.

II. Plaintiffs' Own Choice to Proceed with Depositions Has Resulted in the Prejudice They Now Claim

Plaintiffs' most recent submission largely repeats arguments that have already been addressed. As the Court noted in its May 26 Special Master Order, "Aurobindo has continued to make additional productions and supplement previous productions . . . Plaintiffs have also reserved

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their rights to recall the witnesses pending their review of additional documents received in discovery, and defense counsel has not objected.” ECF No. 1275 at 6–7. To date, the only Aurobindo witness Plaintiffs have asked to bring back is Blessy Johns, Director of Regulatory Affairs. In their May 26 Letter, Plaintiffs now complain that by proceeding with depositions in the first instance, “Plaintiffs have exposed their legal strategy, allowing Aurobindo to prepare its witnesses accordingly for second depositions.” May 26 Letter, ECF No. 1272 at 2.

Plaintiffs have not suffered any prejudice, since Aurobindo has continued to offer to keep those depositions open, and nothing in their letter changes that fact. Plaintiffs’ May 26 Letter focuses specifically on the 30(b)(6) deposition of Sanjay Singh. As Plaintiffs concede, Aurobindo notified Plaintiffs that additional documents were forthcoming six days prior to the Singh deposition, and Aurobindo offered to delay said depositions in order to provide Plaintiffs with additional time. Specifically, Aurobindo offered to postpone the depositions of Sanjay Singh and David Palew in light of the imminent document production.¹ (A copy of defense counsel’s email dated May 14, 2021 and letter dated May 26, 2021 are attached, collectively, as Exhibit A). The weekend before Mr. Singh’s deposition, Aurobindo reviewed and produced documents as quickly as possible. Plaintiffs refused Aurobindo’s offer to postpone and decided instead to proceed with the depositions and leave them open. Aurobindo has not objected to allowing these depositions to remain open.² Since submitting their May 26 letter, Plaintiffs have requested to delay the second Blessy Johns deposition, which had been scheduled for June 17, 2021, until after document production is complete. Plaintiffs withdrew their notice of deposition for Venkat Kota without prejudice.

III. Plaintiffs Have Not Demonstrated Prejudice From Receipt of Additional Metadata

Aurobindo’s supplemental productions were accompanied by a comprehensive metadata overlay production on May 21, which provides a complete update to the All Custodians field in the metadata. Plaintiffs characterize this production as a “ongoing misconduct,” when it is actually the result of Aurobindo’s good faith effort to respond to Plaintiffs’ requests and remedy the deficiencies alleged by Plaintiffs. May 26 Letter, ECF No. 1272 at 2. The latest claims of prejudice by Plaintiffs are meritless.

Plaintiffs assert that this overlay production as “problematic” and suggest that Aurobindo has acted in bad faith by producing this metadata after depositions have been taken. But Plaintiffs’ claims of supposed prejudice are overblown. The vast majority of the files impacted by the overlay productions are emails where the sender and recipients are apparent on the face of email. While the All Custodian field may make searching more convenient, Plaintiffs do not need the All Custodian metadata to determine who was involved with an email or email chain. Plaintiffs have had emails from Aurobindo Pharma Ltd. (“APL”) for months. They have had emails from the U.S. Entities for over a year. It is disingenuous for Plaintiffs to suggest they had no idea which custodians were involved with the emails and claim they are surprised or burdened by the metadata overlays when Plaintiffs’ own motion for sanctions demonstrates their ability to search for email relevant to a given custodian that were not identified by the All Custodian metadata.

¹ Mr. Singh was also intimately involved in resolving an important internal issue the week before his deposition. See Exhibit A, email dated May 14, 2021.

² To date, the only Aurobindo witness Plaintiffs have asked to bring back is Blessy Johns, Director of Regulatory Affairs.

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Moreover, Plaintiffs argue that the addition of custodians to a document may cause Plaintiffs to "re-take depositions." May 26 Letter, ECF No. 1272 at 2. All of the depositions to date have been left open without objection from Aurobindo.

IV. Plaintiffs Repeatedly Misrepresent APL's Document Production

Plaintiffs' assertion that Aurobindo Pharma Ltd. ("APL") "produced only two noncustodial documents (organizational charts)" prior to November 2020 is incorrect. *Id.* at 1. The core discovery produced by APL included, but was not limited to, the following non-custodial files or parts thereof:

- Establishment Inspection Reports, 483 Observations, Warning Letter and responses to the same;
- Drug Master File and amendments to same;
- Communications with FDA;
- Analytical Method Validation Reports;
- Chromatography testing data;
- Nitrosamine testing data;
- Standard Test Procedures;
- Summary of Corrective and Preventative Actions ("CAPAs");
- CAPA implementation reports;
- Report on Identification of Unknown Peaks in GC Methods for All APIs above reporting threshold limit;
- Status Update on Inspection of Manufacturing Equipment & Evaluation of Equipment Suitability;
- Engagement of Third-Party Consulting Firm (Gintegra) to Conduct a Comprehensive, On-Site Assessment of the API Equipment Maintenance and Cleaning Program;
- Nitrosamine Testing of Raw Materials and Solvent Batches;
- Report on Comprehensive Review of Release Specification and Regulatory Specification for All APIs;
- Disposal Details of Recovered Tri N Butyl Tin Chloride Received from Lantech Pharmaceuticals;
- Revised Specification for Valsartan;
- Standard Operating Procedures ("SOPs") on preparation, review, approval, distribution, revisions and retrieval of specifications and standard testing procedures;
- SOPs regarding vendor management;
- Valsartan USP (Process II) Certificates of Analysis;
- Valsartan USP (Process II) Batch Production and Control Records;
- Revised Specifications for Valsartan Key Starting Materials;
- Evaluation Report on GC Unknown Impurity;
- Assessment Report on chromatographic data of Valsartan batches;
- Valsartan Investigation Report

Attached for Your Honor's convenience is a comprehensive production list of APL Core Discovery produced on June 30, 2020 (Exhibit "B"). While the production of these categories of documents may not have been complete before November 2020, this list clearly contradicts Plaintiffs' assertion that APL "produced only two noncustodial documents." May 26 Letter, ECF No. 1272 at 1. Plaintiffs also erroneously claim that APL failed to provide complaint documentation, certificates of analysis, quality agreements, and Standard Operating Procedures. Aurobindo has confirmed production thereof by listing bates numbers.

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V. Sanctions Are Unwarranted

Plaintiffs' May 26 Letter attempts to characterize Aurobindo's supplemental productions as a continuation of willful dilatory behavior when they are, to the contrary, a good faith effort to cure supposed deficiencies and comply with all discovery obligations. There is simply no evidence that Aurobindo has acted in bad faith with the intention to disrupt Plaintiffs' preparation. As Your Honor succinctly stated, "any prejudice suffered . . . has been ameliorated curtailed by the fact that Plaintiffs ultimately obtained, and continue to receive the requested documents at issue, and continue to depose Aurobindo witnesses." Special Master Order No. 21, ECF No. 1275 at 6.

To the best of its knowledge, Aurobindo has now collected all custodial and non-custodial data that may be responsive to Plaintiffs' requests. Further, Aurobindo is aiming to complete production by June 8, 2021. Plaintiffs' latest motion should be denied.

Respectfully,

A handwritten signature in blue ink, appearing to read "John P. Lavelle, Jr.", is positioned below the "Respectfully," text.

John P. Lavelle, Jr.

JPL/dms
Enclosures

c: all counsel of record (via ECF)